

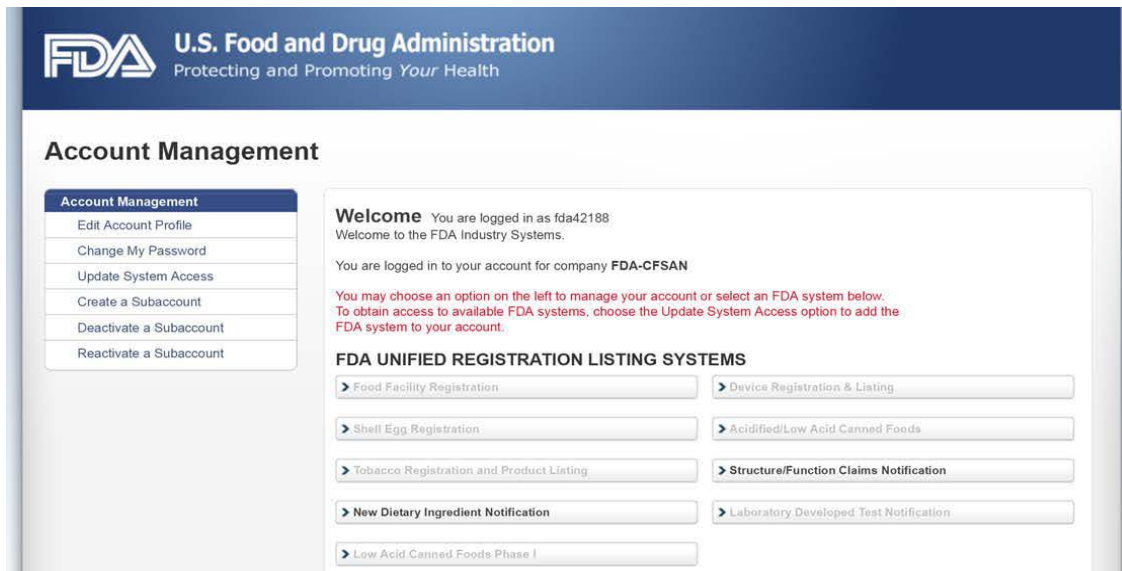
FDA Industry Systems  
New Dietary Ingredient Notification  
Step-by-Step Instructions  
<https://www.access.fda.gov/>

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## Enter a New Dietary Ingredient Notification

After you log into the FDA Industry Systems page, you will need to select the “New Dietary Ingredient Notification” option from the list of systems available on the FURLS Home Page. See **Figure 1** below.

**Figure 1:**



Once you have selected “New Dietary Ingredient Notification”, you will navigate to the NDIN main menu. To begin the notification process, select “Enter New Notification” from the list of options on the left. After you have entered an application and saved it as a draft, you may choose to “Retrieve Draft NDIN” from the main menu. See **Figure 2** below.

**Figure 2:**

The screenshot shows the FDA's 75 Day Premarket New Dietary Ingredient (NDI) Notification website. The header features the U.S. Department of Health and Human Services logo, the FDA NDI logo, and the text "75 DAY PREMARKET NEW DIETARY INGREDIENT (NDI) NOTIFICATION". A "FURLS HOME" link is in the top right. Below the header, the page title is "New Dietary Ingredient (NDI) Notification". A navigation bar includes "NDI Home" with a dropdown arrow. A sidebar on the left lists "NDI Home", "Enter New Notification", "Retrieve Draft NDIN", and "Amendments". The main content area is titled "Welcome" and contains a "PAPERWORK REDUCTION ACT NOTICE". This notice includes form approval details (OMB No. 0910-0330, expiration 03/31/2018), a statement that response is voluntary, an estimated 20-hour completion time, and contact information for the Paperwork Reduction Act (PRA) Staff at [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov). A "Please Note" at the bottom states the system times out after 30 minutes of inactivity.

## STEP 1

Figures 3, 4, 5, 6 and 7 demonstrate the information to be entered into Section 1 of the notification.

### Section 1: Submitter, Notification Owner, and Contact Information

All fields that are not designated as **OPTIONAL** must be completed before moving on to the next screen. If all of the required fields are completed with the appropriate information, the notification will be in compliance with the NDIN regulation, 21 CFR 190.6. If these fields are not filled in as required, the primary contact designated in the notification will receive a response letter from FDA indicating that their application is incomplete.

Please enter the following information about the submitter of the notification in Section 1a and then press the "+ Contact/Update Contact" button at the bottom of the screen, see **Figure 3** below.

<b>Field</b>	<b>Description</b>
<i>Type of Submitter</i>	<p>Please select the type of firm or person that is submitting the NDI notification. Select <b>all</b> that apply.</p> <p>Select “Manufacturer of NDI” if the notification is being submitted by the manufacturer of the NDI.</p> <p>Select “Distributor of NDI” if the notification is being submitted by the distributor of the NDI.</p> <p>Select “Manufacturer of Dietary Supplement Containing NDI” if the notification is being submitted by the manufacturer of a dietary supplement that contains the NDI.</p> <p>Select “Distributor of Dietary Supplement Containing NDI” if the notification is being submitted by the distributor of a dietary supplement that contains the NDI.</p> <p>Select “Agent/ Attorney/ Consultant” if the notification is being submitted by a lawyer, consultant, or other agent on behalf of a manufacturer or distributor of the NDI or of a dietary supplement that contains the NDI.</p>
<i>Company Name</i>	If the submitter is a Company, enter the full name of the company.
<i>Mailing Address Line 1</i>	The street name and number or post office box number for the submitter’s mailing address.
<i>Mailing Address Line 2</i>	This line is <b>optional</b> ; it can be used to enter a building number, suite number, or other information that doesn’t fit on the first line.
<i>Country</i>	The country for the submitter’s mailing address. This section defaults to “United States.” For foreign addresses, select the appropriate country from the pull-down menu.
<i>Zip Code or Postal Code</i>	The zip code for the submitter’s mailing address. For addresses outside the United States, enter the postal code, if any.
<i>City</i>	The city for the submitter’s mailing address.
<i>State or Province</i>	The state, province, or territory for the submitter’s mailing address. Select a state, province, territory, or “Not applicable” from the pull-down menu.

Figure 3:

75 DAY PREMARKET

NEW DIETARY INGREDIENT (NDI) NOTIFICATION

[FURLS HOME](#) | [NDI HOME](#)

New Dietary Ingredient (NDI) Notification

[NDI Home](#) | [Enter New Notification](#)

[Step 1](#)
[Step 2](#)
[Step 3](#)
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[Step 7](#)

[NDI Home](#)
[Enter New Notification](#)
[Search Notification](#)
[Retrieve Draft NDIN](#)
[Summary Reviewer Review](#)
[Draft Letter](#)

### Section 1: Contact Information

This section asks you to identify:

- The Submitter of the notification**  
 The submitter of the notification is the person or firm that submits the online notification to FDA. The submitter could be a manufacturer or distributor of dietary ingredients or dietary supplements, or it could be a person or entity that submits the notification on behalf of a manufacturer or distributor, such as a consultant, law firm, or other agent of the manufacturer or distributor.
- The Owner of the notification**  
 The owner of the notification is the manufacturer or distributor by or on behalf of which the notification is being submitted. In some cases the owner of the notification and the submitter of the notification will be the same, but in others, such as when manufacturers and distributors hire an outside entity (attorney or consultant) to submit the notification on their behalf, the notification owner and the submitter will be different.
- Contacts (primary and additional)**  
 Contacts are people whom you designate to communicate with FDA about the notification. By listing someone as a contact in this section, you authorize FDA to contact him or her with questions about the notification, updates on the status of the notification, and any other matters related to the notification. You must designate at least one person as the primary contact. We encourage you to designate additional contacts in case the primary contact is not available, but that is optional.

[1a. Submitter](#)
[1b. Owner](#)
[1c. Primary Contact](#)
[1d. Other Contact\(s\) \(Optional\)](#)

#### 1a. Submitter of the Notification

Type of Submitter (Select all that apply)

☐ Manufacturer of NDI
 ☐ Distributor of NDI
 ☐ Manufacturer of Dietary Supplement Containing NDI
 ☐ Distributor of Dietary Supplement Containing NDI
 ☐ Agent / Attorney / Consultant

Company Name (If applicable)

Mailing Address Line 1

Mailing Address Line 2 (Optional)

Country

UNITED STATES

ZIP or Postal Code

Please enter "NONE" in the ZIP or Postal Code field if a ZIP or Postal Code is not used in the selected Country

City

Please Select

State or Province

Please Select

Cancel

+ Add / Update Contact

Click to add/update one or more contact(s)

Save And Exit

Next

Enter the following information about the owner of the notification in Section 1b and then press the “+ Add/Update Contact” button at the bottom of the screen, see **Figure 4** below.

<b>Field</b>	<b>Description</b>
<i>Is the owner of the notification the same as the submitter?</i>	Answer “Yes” if the owner of the notification is the same as the submitter of the notification identified in Section 1a. Selecting ‘Yes’ will automatically fill the rest of the fields in Section 1b with the information entered for the submitter of the notification in Section 1a. If you select ‘No,’ you must fill in the rest of the fields in this Section.
<i>Type of Manufacturer or Distributor</i>	<p>Please select all that apply.</p> <p>Select “Manufacturer of NDI” if the owner of the notification is the manufacturer of the NDI.</p> <p>Select “Distributor of NDI” if the owner of the notification is the distributor of the NDI.</p> <p>Select “Manufacturer of Dietary Supplement Containing NDI” if the owner of the notification is the manufacturer of a dietary supplement that contains the NDI.</p> <p>Select “Distributor of Dietary Supplement Containing NDI” if the owner of the notification is the distributor of a dietary supplement that contains the NDI.</p>
<i>Company Name</i>	If the notification owner is a company, enter the full name of the company. Otherwise, enter the full name of the individual.
<i>Mailing Address Line 1</i>	The street name and number or post office box number for the notification owner’s mailing address.
<i>Mailing Address Line 2</i>	This line is <i>optional</i> ; it can be used to enter a building number, suite number, or other information that doesn’t fit on the first line.
<i>Country</i>	The country for the notification owner’s mailing address. Defaults to ‘United States.’ For foreign addresses, select the appropriate country from the pull-down menu.
<i>Zip Code or Postal Code</i>	The zip code for the notification owner’s mailing address. For addresses outside the United States, enter the postal code.
<i>City</i>	The city for the notification owner’s mailing address.
<i>State or Province</i>	The state, province, or territory for the notification owner’s mailing address. Select a state, province, territory, or “Not applicable” from the pull-down menu.

**Figure 4:**

[NDI Home](#)  
[Enter New Notification](#)  
[Search Notification](#)  
[Retrieve Draft NDI/N](#)  
[Summary Receiver Review](#)  
[Draft Letter](#)

Step 1
Step 2
Step 3
Step 4
Step 5
Step 6
Step 7

### Section 1: Contact Information

This section asks you to identify:

- The Submitter of the notification**  
The submitter of the notification is the person or firm that submits the online notification to FDA. The submitter could be a manufacturer or distributor of dietary ingredients or dietary supplements, or it could be a person or entity that submits the notification on behalf of a manufacturer or distributor, such as a consultant, law firm, or other agent of the manufacturer or distributor.
- The Owner of the notification**  
The owner of the notification is the manufacturer or distributor by or on behalf of which the notification is being submitted. In some cases the owner of the notification and the submitter of the notification will be the same, but in others, such as when manufacturers and distributors hire an outside entity (attorney or consultant) to submit the notification on their behalf, the notification owner and the submitter will be different.
- Contacts (primary and additional)**  
Contacts are people whom you designate to communicate with FDA about the notification. By listing someone as a contact in this section, you authorize FDA to contact him or her with questions about the notification, updates on the status of the notification, and any other matters related to the notification. You must designate at least one person as the primary contact. We encourage you to designate additional contacts in case the primary contact is not available, but that is optional.

#### Contacts List

Type	Name	Address	Action
Submitter	abcd	3100 Park Branch Pkwy, College Park, MD 20740-3523 United States	

1a. Submitter
1b. Owner
1c. Primary Contact
1d. Other Contact(s) (Optional)

#### 1b. Owner of the Notification

Is the owner of the notification the same as the submitter?  
☒ Yes ☐ No

Type of Manufacturer or Distributor (Select all that apply)

☐ Manufacturer of NDI

☐ Distributor of NDI

☐ Manufacturer of Dietary Supplement Containing NDI

☐ Distributor of Dietary Supplement Containing NDI

Company Name  
  
If the notification owner is an individual not affiliated with a company enter the full name of the individual in lieu of company name

Mailing Address Line 1  
  
Mailing Address Line 2 (Optional)  
  
Country  
   
ZIP or Postal Code  
  
Please enter NONE in the ZIP or Postal Code field if a ZIP or Postal Code is not used in the selected Country  
City  
   
State or Province  
   
Click to add/update one or more contact(s)

Please specify the primary contact for the notification in Section 1c (see **Figure 5** below). The primary contact is the person designated to communicate (point of contact) with FDA in regard to matters that arise during FDA's review of the notification. The primary contact can be an employee or official of the notification

owner, the notification submitter, or a third party (such as a consultant or attorney). Please provide the following information about the primary contact person in Section 1c and then press the “+ Add/Update Contact” button at the bottom of the screen, see **Figure 5** below.

<b>Field</b>	<b>Description</b>
<i>Type of Contact</i>	<p>Select the type of primary contact authorized to communicate with FDA during the notification review.</p> <p>Select “Submitter of the notification” if the contact is an official or employee of the submitter of the NDIN. Selecting this type will automatically fill the company name and address fields in Section 1c with the information provided for the submitter in section 1a.</p> <p>Select “Owner of the notification” if the contact is an official or employee of the owner of the NDIN. Selecting this type will automatically fill the company name and address fields in section 1c with the information provided for the notification owner in section 1b.</p> <p>Select “Agent/Attorney/Consultant” if the contact is an attorney, consultant, or other agent representing the notification owner.</p> <p>If none of the other selections applies, select “Other” to specify an alternative contact type. Describe the contact’s relationship to the notification owner or submitter in the field provided.</p>
<i>Name of Contact Person</i>	First and last name of the primary contact person.
<i>Company Name</i>	The name of the primary contact person’s company, if any.
<i>Position</i>	Title of the primary contact person.
<i>Mailing Address Line 1</i>	The street name and number or post office box number for the primary contact’s mailing address.
<i>Mailing Address Line 2</i>	This line is <i>optional</i> ; it can be used to enter a building number, suite number, or other information that doesn’t fit on the first line.
<i>Country</i>	The country for the primary contact’s mailing address. Defaults to ‘United States.’ For foreign contacts, select the appropriate country from the pull-down menu.
<i>Zip Code (Postal Code)</i>	The zip code for the primary contact’s mailing address. For



<b><i>Field</i></b>	<b>Description</b>
	addresses outside the United States, enter the postal code, if any.
<i>City</i>	The city for the primary contact's mailing address.
<i>State or Province</i>	The state, province, or territory for the primary contact's mailing address. Select a state, province, territory, or "Not applicable" from the pull-down menu.
<i>Telephone Number</i>	The telephone number of the primary contact person.
<i>Fax Number</i>	The telephone number of the primary contact person's fax machine.
<i>Email Address</i>	An electronic mail address for the primary contact person.

Figure 5:

NDI Home

Enter New Notification

NDI Home

Enter New Notification

Search Notification

Retrieve Draft NDI

Summary Reviewer Review

Draft Letter

Step 1

Step 2

Step 3

Step 4

Step 5

Step 6

Step 7

## Section 1: Contact Information

This section asks you to identify:

- The Submitter of the notification**  
The submitter of the notification is the person or firm that submits the online notification to FDA. The submitter could be a manufacturer or distributor of dietary ingredients or dietary supplements, or it could be a person or entity that submits the notification on behalf of a manufacturer or distributor, such as a consultant, law firm, or other agent of the manufacturer or distributor.
- The Owner of the notification**  
The owner of the notification is the manufacturer or distributor by or on behalf of which the notification is being submitted. In some cases the owner of the notification and the submitter of the notification will be the same, but in others, such as when manufacturers and distributors hire an outside entity (attorney or consultant) to submit the notification on their behalf, the notification owner and the submitter will be different.
- Contacts (primary and additional)**  
Contacts are people whom you designate to communicate with FDA about the notification. By listing someone as a contact in this section, you authorize FDA to contact him or her with questions about the notification, updates on the status of the notification, and any other matters related to the notification. You must designate at least one person as the primary contact. We encourage you to designate additional contacts in case the primary contact is not available, but that is optional.

### Contacts List

Type	Name	Address	Action
Submitter	abcd	5100 Paint Branch Pkwy, College Park, MD 20740-3535 United States	
Owner	abcd	5100 Paint Branch Pkwy, College Park, MD 20740-3535 United States	

1a. Submitter

1b. Owner

1c. Primary Contact

1d. Other Contact(s) (Optional)

### 1c. Primary Contact

Type of Contact

☒ Submitter of the Notification  
☐ Owner of the Notification  
☐ Agent / Attorney / Consultant  
☐ Other (please specify)

Print Name of Contact (Person)

John

Last Name of Contact (Person)

Doe

Company Name (If applicable)

abcd

Position (Optional)

Telephone Number

001 410 5555555

Fax Number (Optional)

001

Email Address

john.doe@abcd.com

Mailing Address Line 1

5100 Paint Branch Pkwy

Mailing Address Line 2 (Optional)

Country

UNITED STATES

ZIP\* or Postal Code

20740

Please enter "NONE" in the ZIP or Postal Code field if a ZIP or Postal Code is not used in the selected Country

City

College Park

State or Province

Maryland

Click to add/update one or more contact(s)

In Section 1d enter the following information for each additional contact that you wish to designate. To add more than one additional contact, enter the contact information and press the button “Add Contact.”

<b>Field</b>	<b>Description</b>
<i>Type of Contact</i>	<p>Select the type of contact.</p> <p>Select “Submitter of the Notification” if the contact is an official or employee of the submitter of the NDIN. Selecting this type will automatically fill the company name and address fields in Section 1c with the information provided for the submitter in Section 1a.</p> <p>Select “Owner of the Notification” if the contact is an official or employee of the owner of the NDIN. Selecting this type will automatically fill the company name and address fields in Section 1c with the information provided for the notification owner in Section 1b.</p> <p>Select “Agent/Attorney/Consultant” if the contact is an attorney, consultant, or other agent for the notification owner.</p> <p>If none of the other selections applies, select “Other” to specify an alternative contact type. Describe the contact’s relationship to the notification owner or submitter in the field provided.</p>
<i>Name of Contact Person</i>	First and last name of the contact person.
<i>Company Name</i>	The name of the contact person’s company, if applicable.
<i>Position</i>	Title of the contact person.
<i>Mailing Address Line 1</i>	The street name and number or post office box number for the contact’s mailing address.
<i>Mailing Address Line 2</i>	This line is <b>optional</b> ; it can be used to enter a building number, suite number, or other information that doesn’t fit on the first line.
<i>Country</i>	The country for the other contact’s mailing address. This section defaults to “United States.” For foreign contacts, select the appropriate country from the pull-down menu.
<i>Zip Code (Postal Code)</i>	The zip code for the contact’s mailing address. For addresses outside the United States, enter the postal code, if any.
<i>City</i>	The city for the contact’s mailing address.

<b><i>Field</i></b>	<b>Description</b>
<i>State or Province</i>	The state, province, or territory for the contact's mailing address. Select a state, province, territory, or "Not applicable" from the pull-down menu.
<i>Telephone Number</i>	The telephone number of the contact person.
<i>Fax Number</i>	The telephone number of the contact person's fax machine.
<i>Email Address</i>	An electronic mail address for the contact person.

Other contacts authorized to communicate with FDA during the notification review should be specified in Section 1d (see **Figure 6** below). Additional contacts may also be designated in a separate letter sent as an amendment to the notification at a later date. FDA reviewers will communicate only with authorized contacts.

Figure 6:

[NDI Home](#) > [Enter New Notification](#)

NDI Home

Enter New Notification

Search Notification

Retrieve Draft NDIN

Summary Reviewer Review

Draft Letter

Step 1

Step 2

Step 3

Step 4

Step 5

Step 6

Step 7

## Section 1: Contact Information

This section asks you to identify:

- The Submitter of the notification**  
The submitter of the notification is the person or firm that submits the online notification to FDA. The submitter could be a manufacturer or distributor of dietary ingredients or dietary supplements, or it could be a person or entity that submits the notification on behalf of a manufacturer or distributor, such as a consultant, law firm, or other agent of the manufacturer or distributor.
- The Owner of the notification**  
The owner of the notification is the manufacturer or distributor by or on behalf of which the notification is being submitted. In some cases the owner of the notification and the submitter of the notification will be the same, but in others, such as when manufacturers and distributors hire an outside entity (attorney or consultant) to submit the notification on their behalf, the notification owner and the submitter will be different.
- Contacts (primary and additional)**  
Contacts are people whom you designate to communicate with FDA about the notification. By listing someone as a contact in this section, you authorize FDA to contact him or her with questions about the notification, updates on the status of the notification, and any other matters related to the notification. You must designate at least one person as the primary contact. We encourage you to designate additional contacts in case the primary contact is not available, but that is optional.

### Contacts List

Type	Name	Address	Action
Submitter	abcd	5100 Park Branch Pkwy, College Park, MD 20740-3525 United States	
Owner	abcd	5100 Park Branch Pkwy, College Park, MD 20740-3525 United States	
Primary	John Doe	5100 Park Branch Pkwy, College Park, MD 20740-3525 United States	

1a. Submitter

1b. Owner

1c. Primary Contact

1d. Other Contact(s) (Optional)

#### 1d. Other Contact(s) (Optional)

To add a contact, you must complete the following fields: Type of Contact, First Name of Contact Person, Last Name of Contact Person, Mailing Address Line 1, City, State or Province, ZIP or Postal Code, Country and either the Telephone Number or the Email Address.

Type of Contact

☐ Submitter of the Notification  
☐ Owner of the Notification  
☐ Agent / Attorney / Consultant  
☐ Other (please specify)

First Name of Contact Person

Last Name of Contact Person

Company Name (if applicable)

Location (Optional)

Telephone Number

Fax Number (Optional)

Email Address

Mailing Address Line 1

Mailing Address Line 2 (Optional)

Country

ZIP or Postal Code

Please enter "NONE" in the ZIP or Postal Code field if a ZIP or Postal Code is not used in the selected Country

City

State or Province

Click to add/update one or more contact(s)

## STEP 2

### Section 2: General Administrative Information

The form for Section 2 is shown in **Figure 7** below. Section 2 contains general administrative information pertaining to the New Dietary Ingredient Notification.

**Figure 7:**

The screenshot displays the FDA's 75 Day Premarket New Dietary Ingredient (NDI) Notification form. The header includes the U.S. Department of Health and Human Services logo, the FDA NDI logo, and the title "75 DAY PREMARKET NEW DIETARY INGREDIENT (NDI) NOTIFICATION". Navigation links for "FURLS HOME" and "NDI HOME" are present. The main heading is "New Dietary Ingredient (NDI) Notification". A breadcrumb trail shows "NDI Home" and "Enter New Notification". A progress bar at the top indicates steps 1 through 7, with Step 2 currently selected. On the left, a sidebar menu lists: "NDI Home", "Enter New Notification" (highlighted), "Search Notification", "Retrieve Draft NDIN", "Summary Reviewer Review", and "Draft Letter". The main content area is titled "Section 2: General Administrative Information" and contains five numbered questions, each with radio button options:

1. Name of the New Dietary Ingredient
2. Have you designated information in your notification that you view as a trade secret or as confidential commercial information? (Check one)  
☐ Yes, see attached designation of confidential information  
☐ Yes, information is designated at the place where it occurs in the notification  
☐ No
3. Are you providing a redacted copy of some or all of the notification? (Check one)  
☐ Yes, redacted copy of complete notification  
☐ Yes, redacted copy of part(s) of the notification  
☐ No
4. Are all citations to published information accompanied by reprints or full photostatic copies of the publications? (Check one)  
☐ Yes  
☐ No
5. Are the notification and all publications submitted in English or accompanied by a complete and accurate English translation? (Check one)  
☐ Yes  
☐ No

At the bottom, there are three buttons: "Previous", "Save And Exit", and "Next".

<b>Field</b>	<b>Description</b>
<i>1. Name of the New Dietary Ingredient</i>	Enter the name of the new dietary ingredient that is the subject of the notification. Please note that for an NDI notification concerning a NDI that is a combination of two or more ingredients, the NDI notification should include safety information for each ingredient as part of the safety information for the NDI notification as a whole.
<i>2. Have you designated information in your notification that you view as a trade secret or confidential commercial information? (Check one)</i>	<p>Select "Yes, see attached designation of confidential information" if there are trade secrets or confidential commercial information in the notification and you are providing an attachment detailing the information you view as confidential. This attachment should be uploaded in Section 5.</p> <p>Select "Yes, information is designated at the place where it occurs in the notification" if you have marked certain material as confidential within the notification.</p> <p>Select "No" if you do not consider any of the information in the notification to be a trade secret or confidential commercial information.</p>
<i>3: Are you providing a redacted copy of some or all of the notification? (Check one)</i>	<p>Select "Yes, redacted copy of complete notification" if you are redacting individual words or sentences throughout the notification. You can send in a redacted copy of the entire notification with these words or sentences blacked out. The redacted copy should be uploaded as an attachment in Section 5.</p> <p>Select "Yes, redacted copy of part(s) of the notification" if you are redacting sections or multiple pages of your notification. You can provide a description of the portions that you want redacted, e.g., "Please redact section 6 from pages 90 – 299 which include data from a 90-day chronic animal study we sponsored." The redacted copy should be uploaded as an attachment in Section 5.</p> <p>Select "No" if you are not including a redacted copy of your notification.</p>
<i>4: Are all citations to published information accompanied by reprints or full photostatic copies of the publication? (Check one)</i>	<p>Select "Yes" if the notification includes reprints or photocopies of all of the publications that were cited.</p> <p>Select "No" if the notification cites publications and does not include reprints or photocopies of all of the publications that were cited. If you select "No" your notification will be incomplete and you will not be able to transmit it to FDA.</p>
<i>5: Are the notification and all publications submitted in English or accompanied by a complete and accurate English translation? (Check one)</i>	<p>Select "Yes" if the entire notification, including any supporting publications, is in English or if the notification includes a complete and accurate English translation of any foreign language materials submitted.</p> <p>Select "No" if any part of the notification, including supporting publications, is being submitted in a foreign language without a complete and accurate English translation. If you select "No," your notification will be incomplete and you will not be able to transmit it to FDA</p>

## STEP 3

### Section 3: Description of New Dietary Ingredient and Dietary Supplement

Please describe the new dietary ingredient and the dietary supplement that contains the new dietary ingredient by answering the questions in Section 3 (see **Figure 8** below).

**Figure 8:**

The screenshot shows the FDA's 75 Day Premarket New Dietary Ingredient (NDI) Notification form. The header includes the FDA logo, the text "75 DAY PREMARKET NEW DIETARY INGREDIENT (NDI) NOTIFICATION", and links for "FURLS HOME" and "NDI HOME". The main title is "New Dietary Ingredient (NDI) Notification". Below this is a navigation bar with "NDI Home" and "Enter New Notification". A sidebar on the left contains links: "NDI Home", "Enter New Notification" (highlighted), "Search Notification", "Retrieve Draft NDIN", "Summary Reviewer Review", and "Draft Letter". The main content area is titled "Section 3: Description of NDI and Dietary Supplement Containing the NDI" and features a progress bar with steps 1 through 7. Step 3 is currently active. The form is divided into three main sections: 1. New Dietary Ingredient Type (Check all that apply). This section includes checkboxes for Vitamin, Mineral, Herb or other botanical, Amino acid, and Dietary substance for use by man to supplement the diet by increasing the total dietary intake. It also includes a checkbox for Concentrate, metabolite, constituent, extract, or combination of any ingredient described above. 2. Name of the new dietary ingredient and related information. This section includes a text box for "Maximum level of new dietary ingredient in each serving of dietary supplement (include units)" with a "150" button. It also includes text boxes for "NDI Name" (containing "EFGH"), "Latin Binomial Name (LBN)", "Synonyms and Trade Name", "Author of LBN", and "Plant Part and Strain". 3. Dietary supplement serving form (Check all that apply). This section includes checkboxes for Tablet, Capsule, Powder, Softgel, Liquid, Gelcap, Sachet, and Other. It also includes a section for "Check Other in the following cases:" with two numbered options: 1. You are a bulk ingredient supplier (check serving forms recommended, and specify "bulk ingredient supplier" in the text box below) and 2. You have an alternative serving form (specify the serving form in the text box below). A text box is provided for the alternative serving form.

U.S. Department of Health and Human Services

**FDA** **75 DAY PREMARKET**  
NEW DIETARY INGREDIENT (NDI) NOTIFICATION

FURLS HOME | NDI HOME

New Dietary Ingredient (NDI) Notification

NDI Home | Enter New Notification

Step 1 Step 2 Step 3 Step 4 Step 5 Step 6 Step 7

**Section 3: Description of NDI and Dietary Supplement Containing the NDI**

1. New Dietary Ingredient Type (Check all that apply)  
(Synonyms and Trade Name, Plant Part and Strain, Latin Binomial Name (LBN) and Author of LBN must be completed when "Herb or other botanical" is selected in Question 1.)

☐ Vitamin ☐ Dietary substance for use by man to supplement the diet by increasing the total dietary intake

☐ Mineral ☐ Concentrate, metabolite, constituent, extract, or combination of any ingredient described above

☐ Herb or other botanical

☐ Amino acid

2. Name of the new dietary ingredient and related information

Maximum level of new dietary ingredient in each serving of dietary supplement (include units)

150

NDI Name: EFGH

Latin Binomial Name (LBN)

Synonyms and Trade Name

Author of LBN

Plant Part and Strain

3. Dietary supplement serving form (Check all that apply)  
If you are a bulk supplier, describe formulations that are recommended for your NDI.

☐ Tablet ☐ Other

☐ Capsule

☐ Powder

☐ Softgel

☐ Liquid

☐ Gelcap

☐ Sachet

Check Other in the following cases:

1. You are a bulk ingredient supplier (check serving forms recommended, and specify "bulk ingredient supplier" in the text box below)

2. You have an alternative serving form (specify the serving form in the text box below)



**Figure 8 (cont):**

4. Description of dietary supplement (Include the level of NDI and all other ingredients in one unit of the dietary supplement. If the notification concerns an NDI that is a combination of two or more other NDIs, you should provide the following information for each component NDI: Synonyms, Trade Name, Plant Part, Strain, Latin Binomial Name, Author of Latin Binomial Name, and NDI type. Where relevant, also include the following additional information: CAS registry number, Unusual form (e.g., malted barley or immature apples), Type of manufacture (e.g., greater than 99% purity, 50:1 dry leaf extract, or fermentation product)).

512

---

5. Conditions of Use of the Dietary Supplement

5a. Serving instructions (e.g., "take with food", "take before bed", "dissolve in a glass of water", etc).

512

5b. Dietary supplement serving size (weight or volumetric measure), serving frequency (# of servings/day, interval between servings), duration of use and maximum total daily intake level

512

5c. Target populations / excluded populations / other restrictions

512

---

6. Other (Optional)

512

---

Previous

Save And Exit

Next

Please enter in Section 3 the following information about the new dietary ingredient.

<b>Field</b>	<b>Description</b>
<b>1. New Dietary Ingredient Type (Check all that apply)</b>	<p>Select the type of dietary ingredient that best describes the new dietary ingredient that you wish to introduce, using the categories provided.</p> <p>If more than one category applies then select all of the applicable categories; e.g., for vanilla extract you would check the “herb or other botanical,” “dietary substance,” and “concentrate, metabolite, constituent, extract, or combination” boxes.</p>
<b>2: New dietary ingredient name and related information</b>	<p>Enter the maximum level of the NDI (including units of measurement) in a serving of the dietary supplement, if your notification applies to a specific dietary supplement. If you are a bulk supplier or if your notification is intended to cover dietary supplements at a range of doses, enter the maximum level of the NDI (including units of measurement) per serving that you have concluded will reasonably be expected to be safe under the conditions of use described in the notification.</p> <p>The NDI name you entered in Section 2 will be filled in for you in the first field below the maximum serving level.</p> <p>Next, list the trade name of the NDI and any synonyms for the NDI (other names under which the NDI is known) that should be used to search the scientific literature about the safety of the NDI.</p> <p>For botanical and microbial NDIs, enter the following additional pieces of information:</p> <ul style="list-style-type: none"> <li>• The plant part and plant strain from which the NDI is taken. (For microbial NDIs, enter the microbial strain.)</li> <li>• The Latin binomial name.</li> <li>• The author of the Latin binomial name (if applicable).</li> </ul>
<b>3: Dietary supplement serving form (Check all that apply)</b>	<p>Select the form of the dietary supplement that contains the NDI. If the NDI will be an ingredient of dietary supplements in more than one form, select all of the forms that apply. If the form of your dietary supplement is not listed, select “Other” and describe the form in the text box provided. If you are a bulk ingredient supplier, select “Other”, enter “Bulk Ingredient Supplier” in the text box, and select the forms that you recommend. If the serving form you recommend is not listed, describe the form in the text box provided after “Bulk Ingredient Supplier.”</p>
<b>4: Description of dietary supplement (Include level of the NDI and all other ingredients in one unit of the dietary supplement)</b>	<p>List the names and levels of all of the ingredients in each dietary supplement that contains the new dietary ingredient. Provide the level per unit (i.e., capsule, tablet, etc.) of the dietary supplement, not per serving of the dietary supplement. The level should correspond to the level in a specified serving form in Question 3. You should list both dietary ingredients and other ingredients for each supplement.</p> <p>If the notification concerns a NDI that is a combination of two or more</p>

<b>Field</b>	<b>Description</b>
	<p>other ingredients, you should provide the following information for each component of the NDI: Synonyms, Trade Name, and NDI type (using categories from Question 1). Where relevant, you should also include the following additional information for each component NDI: Plant Part, Strain, Latin Binomial Name, Author of Latin Binomial Name, CAS registry number, Unusual form (e.g., malted barley or immature apples), Type of manufacture (e.g., &gt;99% purity, 50:1 dry leaf extract, or fermentation product).</p> <p>If you are a bulk ingredient supplier, provide the requested information about NDI level, other ingredients, form, and type of manufacture based on the conditions of use that you recommend for your NDI and for which you have a reasonable expectation of safety based on history of use or other evidence.</p> <p>If the notification is intended to cover more than one dietary supplement that contains the NDI, enter the description of the first dietary supplement here, and enter the descriptions of the remaining dietary supplements in the safety information attachment you will upload in Section 4.</p>
<i>5: Conditions of Use of the Dietary Supplement</i>	<p>Provide information detailing the conditions of use for each dietary supplement that contains the NDI.</p> <p>If you are a bulk ingredient supplier, provide the conditions of use you recommend for dietary supplements that contain the NDI.</p> <p>If the notification is intended to cover more than one dietary supplement that contains the NDI, enter the conditions of use for the first dietary supplement here, and enter the conditions of use for the remaining dietary supplements in the safety information attachment you will upload in Section 4.</p>
<i>5a: Serving Instructions (e.g., “take with food,” “take before bed,” “dissolve in a glass of water,” etc.)</i>	Provide information on the serving instructions (directions for use) for each dietary supplement that contains the NDI.
<i>5b: Dietary supplement serving size (weight or volumetric measure), serving frequency (# of servings/day, interval between servings), duration of use and maximum total daily intake level</i>	For each dietary supplement that contains the NDI, provide information on the dietary supplement serving size (weight or volumetric measure of one serving of the dietary supplement), serving frequency (number of servings per day, length of time between servings), duration of use, and maximum daily intake level (weight or volumetric measure) of the dietary supplement when taken that are represented in its labeling.
<i>5c: Target populations/excluded populations/other restrictions</i>	For each dietary supplement that contains the NDI, provide information on the population groups for which the product is intended and on any population groups that should not take the product. For example, you may want to state that the dietary supplement should not be taken by pregnant and lactating women or by individuals with certain medical conditions: (e.g., diabetics or individuals unable to metabolize phenylalanine.) Also provide information on any other use restrictions

<b>Field</b>	<b>Description</b>
	that may apply. For example, if the intake of the NDI or one of the other dietary ingredients in the supplement needs to be limited for safety reasons, you may want to state that the dietary supplement should not be taken in combination with other dietary supplements that contain the same dietary ingredient.
6: <i>Other</i>	Please provide any additional information describing the NDI and the dietary supplement(s) that contains the NDI. This field can also be used as additional space to enter information in response to the questions in this section.

## STEP 4

This section must be completed in order to proceed to the next screen.

### **Section 4: Safety Information Attachment (see Figure 9 below)**

In this section, you will download and complete a safety information template that describes the scientific information on which you base your conclusion that the dietary supplement(s) that contains the NDI will reasonably be expected to be safe. Safety information includes, among other things, information demonstrating that the NDI is identical or related to substances documented as having a history of use as food and/or to test articles used in safety studies. In addition, safety information means providing a thorough documentation of the history of use as food, and the results of safety studies, including genetic toxicology studies, pharmacokinetic studies, animal toxicology studies and human clinical studies. The template asks for details about the identity of the NDI, verification of that identity, information about its history of use as food, and/or other evidence relevant to the safety of the NDI and the dietary supplement. The template also asks for reprints or photostatic copies of all cited studies. After filling in the template, you must upload the completed safety information template file and files that contain the scientific publications cited in your notification.

**Figure 9:**

U.S. Department of Health and Human Services

**FDA NDI** | **75 DAY PREMARKET**  
NEW DIETARY INGREDIENT (NDI) NOTIFICATION

FURLS HOME | NDI HOME

## New Dietary Ingredient (NDI) Notification

NDI Home ☐ Enter New Notification

NDI Home ☐ Enter New Notification ☐ Search Notification ☐ Retrieve Draft NDIN ☐ Summary Reviewer Review ☐ Draft Letter

Step 1 Step 2 Step 3 **Step 4** Step 5 Step 6 Step 7

### Section 4: Safety Information Attachment

In this section, you will download and fill in a safety information template describing the scientific information on which you base your conclusion that the dietary supplement(s) containing the NDI will reasonably be expected to be safe. Safety information means, among other things, information showing that the NDI is identical or related to substances documented as having a history of use as food and/or to test articles used in safety studies. In addition, safety information means documentation of history of use as food, and the results of safety studies, including, genetic toxicology studies, pharmacokinetic studies, animal toxicology studies and human clinical studies. The template asks for details about the identity of the NDI, verification of that identity, information about history of use as food and/or other evidence relevant to the safety of the NDI and the dietary supplement. After filling in the template, you will upload the completed template to your notification and attach files containing the scientific publications cited in your notification.

**Please ensure that you do not upload a password protected document. Maximum allowed file size is 2GB. Accepted file types are .doc, .docx, .rtf, and .pdf. Click [here](#) to download the Safety Information template file.**

**Select Next to proceed to Section 5. You will be able to upload documents for Section 4 and Section 5 in subsequent screens.**

**To upload your document at a later time, select Save & Exit to save a draft of the notification. Once you are ready to upload your documents, select 'Retrieve Draft NDIN' from the NDI Main Menu to complete your NDI Notification.**

☐ Previous ☐ Save And Exit ☐ Next

To download the template file that is provided for entering your safety information, click on the blue link in the sentence “Click [here](#) to download the Safety information template file.” After you have downloaded the template file, fill out all of sections in the template with the requested information pertaining to your NDI and the dietary supplement(s) that contains the NDI, attach any published and unpublished articles cited within the notification, and save the completed template to your computer in one of the supported file formats (doc, docx, rtf, or pdf). You may find it advantageous to combine the completed safety information template file and the files that contain cited studies in one file, and upload this single file in the section called “Safety Information Attachment.” Alternatively, you may attach the files that contain cited studies separately by combining these files into a single file for each of the following: identity, history of use and other evidence of safety, and attach these three files in the

Optional Section called “Additional Attachments” (See Section 5). You will be prompted to upload the attachments that are pertinent to Sections 4 and 5 in subsequent screens.

## STEP 5

### Section 5: Additional Attachments (*This is an optional section*)

Any additional attachments that might be included with the NDI notification are explained in Section 5 (see **Figure 10** below). You should clearly identify the attachments with appropriately descriptive file names (for example: first author, year, and title or paraphrase of title for publications). The page numbers in each attachment should be numbered consecutively.

**Figure 10.**

U.S. Department of Health and Human Services

FDA NDI

75 DAY PREMARKET  
NEW DIETARY INGREDIENT (NDI) NOTIFICATION

FURLS HOME | NDI HOME

New Dietary Ingredient (NDI) Notification

NDI Home > Enter New Notification

NDI Home

Enter New Notification

Search Notification

Retrieve Draft NDIN

Summary Reviewer Review

Draft Letter

Step 1 Step 2 Step 3 Step 4 Step 5 Step 6 Step 7

### Section 5: Additional Attachments (*Optional*)

Attachments uploaded here may include the following:

- Product labels (NDI bulk product label or label for dietary supplement containing the NDI)
- Letter designating additional contacts authorized to communicate with the FDA
- Additional safety information provided as an amendment to the submitted notification
- A redacted copy of the notification, or a list of information in the notification that the submitter considers to be trade secrets or confidential commercial information

Clearly identify the attachments with appropriate descriptive file names (for example, first author, year and title, or paraphrase of title, for publications). Number the pages in each attachment consecutively. If you need to correct an attachment or add a new attachment after submitting your notification, email FDA at [NDITEAM@fda.hhs.gov](mailto:NDITEAM@fda.hhs.gov) and we will send you a link that will allow you to upload additional attachments in Section 5. Although you cannot change an attachment once the notification has been submitted, you can upload an amendment to the attachment explaining what information needs to be changed. If you provide additional safety information during the FDA review of the notification, FDA may find that the information provided is substantive, which would reset the filing date of your notification.

**Maximum file size is 2GB. Accepted file types are .doc, .docx, .png, .pdf, .rtf, .png, .jpeg, .jpg, .gif, .bmp, .dif, .jpg, .jfif, .tif and .tiff.**

**Select Save and Upload to save a draft of the Notification and navigate to the NDI Document Upload Screen.**

**Please Note:** The system will prompt you to enter your password prior to the file upload.

Previous Save And Upload

Attachments that are uploaded in this section may include the following: Product labels

(label for dietary supplements that contain the NDI or NDI bulk label), letter designating additional contacts authorized to communicate with the FDA during the notification review, additional safety information provided as an amendment to the notification, redacted copy of the notification, or list of information you believe is trade secret or confidential commercial information for FDA's consideration. If you upload the labeling for the dietary supplement that contains the NDI it will facilitate FDA's evaluate regarding the conditions of use that you recommended or suggested. If you are the manufacturer or distributor of the NDI and do not have access to labeling for the dietary supplement(s) in which the NDI will be used, please upload the labeling of the bulk NDI. Buttons are provided for adding, editing and deleting attachments. If you need to correct an attachment or add a new attachment after the notification has been submitted, contact FDA at [NDITEAM@fda.hhs.gov](mailto:NDITEAM@fda.hhs.gov) and we will set the status of your application such that, for 5 days, the system will allow you to upload additional attachments. Although you cannot change an attachment once your notification has been submitted to the FDA, you can upload an amendment that explains what information needs to be changed.

To save a draft of the notification in preparation for uploading your attachments, press the button "Save and Upload," located on the far right on the bottom of the screen. The next screen is the confirmation screen, which provides you with a draft reference ID and a deadline to submit the draft notification (see **Figure 11** below). Click on the blue link in the sentence "Click [here](#) to begin your upload" at the bottom of the screen, and you will be directed to the screen "NDI Document Upload" to begin selecting files to upload.

**Figure 11.**

The screenshot shows the FDA's 75 Day Premarket New Dietary Ingredient (NDI) Notification system interface. At the top, the header includes the U.S. Department of Health and Human Services logo, the FDA NDI logo, and the text "75 DAY PREMARKET NEW DIETARY INGREDIENT (NDI) NOTIFICATION". Navigation links for "FURLS HOME" and "NDI HOME" are also present.

The main content area is titled "New Dietary Ingredient (NDI) Notification" and includes a breadcrumb trail: "NDI Home > Enter New Notification". A sidebar on the left contains a menu with the following options: "NDI Home", "Enter New Notification" (highlighted in blue), "Search Notification", "Retrieve Draft NDIN", "Summary Reviewer Review", and "Draft Letter".

The main content area displays a "DRAFT CONFIRMATION" message. It states: "Your partially completed NDI Notification has been saved as a draft. The draft reference ID is JOHN000386." It then provides instructions: "The next step to complete your notification is to upload your safety information and any additional documents. The system will display a new window and you will be prompted to browse and upload files." It also mentions: "Once you have finished uploading your documents, select 'Retrieve Draft NDIN' from the NDI Main Menu to complete your NDI Notification." A deadline is specified: "You have until 06/27/2015 to submit the notification. If you fail to submit the NDI Notification by this date, it will be removed." At the bottom of the confirmation message, there is a blue link: "Click [here](#) to begin your upload."

A "Print" button is located at the bottom right of the main content area.

## Submitting an NDIN Electronically and NDI Document Upload:

**Figures 12, 13, and 14** illustrate the screens you will see as you navigate away from the electronic submission portal to the “NDI Document Upload” section. The first screen for the “NDI Document Upload” includes a description of the “Safety Information Attachment” section of the notification at the top half of the screen (see **Figure 12** below) and the description of Section 5 of the electronic submission portal (Additional Attachments) at the bottom half of the screen (see **Figure 13** below). Under the “Safety Information Attachment” heading, you will see a box captioned “Add Attachment.” Click on the “Browse” button in the box to locate the safety information file with the completed template on your computer and select it, and then click “Upload”. Then scroll down to the “Additional Attachments” heading and locate the box captioned “Add Attachment(s)” below it. Click on the “Browse” button in the box to locate any additional attachments (e.g., publications you are submitting in support of your notification) on your computer, select them, and then click “Upload”. Click the Submit button at the bottom of the screen to attach the uploaded documents to your draft notification. A confirmation that the attachments have been uploaded will appear and explain the next step that is required to complete the notification. After you have uploaded the attachments to your notification, click on the blue link in the sentence “Click [here](#) to go to FURLS Home” at the bottom of the screen, and you will be directed to the screen “FURLS Home” to retrieve the draft notification from the NDI Home Main Menu and continue with the electronic submission at Step 6. In Step 6, you will be given the opportunity to review the information you have entered and make changes before submitting the notification to FDA.

**Figure 12:**

**FDA NDI 75 DAY PREMARKET**  
NEW DIETARY INGREDIENT (NDI) NOTIFICATION

New Dietary Ingredient (NDI) Notification

NDI Documents Upload

### NDI Notification Upload - Safety Information Attachment

Here you will upload the safety information file describing the scientific information on which you base your conclusion that the dietary supplement(s) containing the NDI will reasonably be expected to be safe. Safety information means, among other things, information showing that the NDI is identical or related to substances documented as having a history of use as food and/or to test articles used in safety studies. In addition, safety information means documentation of history of use as food, and the results of safety studies, including, genetic toxicology studies, pharmacokinetic studies, animal toxicology studies and human clinical studies. The safety file contains your response to questions about the identity of the NDI, verification of that identity, information about history of use as food and/or other evidence relevant to the safety of the NDI and the dietary supplement.

Please ensure that you do not upload password protected document. Maximum allowed file size is 2GB. Accepted file types are .doc, .docx, .rtf, and .pdf. Click [here](#) to download the Safety Information template file.

Name of Attachment	Size (KB)	Date of Upload	Action
<div><div> Add...</div><div> Remove</div><div> Retry failed</div><div> 0</div><div> 0</div><div> 0</div><div></div></div> <div>Drop Files Here</div> <div><div>Start Upload</div><div>No files</div></div>			



**Figure 13:**

## NDI Notification Upload - Additional Attachments (Optional)










Attachments uploaded here may include the following:

- Product labels (NDI bulk product label or label for dietary supplement containing the NDI)
- Letter designating additional contacts authorized to communicate with the FDA
- Additional safety information provided as an amendment to the submitted notification
- A redacted copy of the notification, or a list of information in the notification that the submitter considers to be trade secrets or confidential commercial information

Clearly identify the attachments with appropriate descriptive file names (for example, first author, year and title, or paraphrase of title, for publications). Number the pages in each attachment consecutively.

Maximum file size is 2GB. Accepted file types are .doc, .docx, .png, .pdf, .rtf, .jpeg, .jpg, .gif, .bmp, .tif, .tiff and .tiff.

### Add Attachment(s)

Name of Attachment	Size (KB)	Date of Upload	Action
<div><div> U.S. Food and Drug Administration</div><div><div> Add...</div><div> Remove</div><div> Retry failed</div><div> 0</div><div> 0</div><div> 0</div><div> 0</div><div></div></div><div><div>Drop Files Here</div><div><div>Start Upload</div><div>No files</div></div></div></div>			

Submit

The next screen (see **Figure 14** below) confirms that the attachments have been uploaded, and explains the next step that is required to complete the notification. After you have uploaded the attachments to your notification, close this screen and wait for an e-mail (that will be sent to the designated Point of Contact at the beginning of the notification submission process) stating that your documents have been scanned and processed.

**Figure 14:**

The screenshot shows the 'New Dietary Ingredient (NDI) Notification' page. At the top, there is a dark blue header with the FDA NDI logo and the text '75 DAY PREMARKET NEW DIETARY INGREDIENT (NDI) NOTIFICATION'. Below the header, the page title 'New Dietary Ingredient (NDI) Notification' is displayed. The main content area is titled 'UPLOAD CONFIRMATION' and contains the following text: 'Your partially completed NDI Notification has been saved as a draft. The draft reference ID is JOHN000395. You have successfully completed uploading your document(s). The system will perform a virus scan for the uploaded documents. You will be notified when the scan is complete. After receiving the scan result notification, the next step is to complete your notification by selecting 'Retrieve Draft NDIN' from the NDI Main Menu.' A 'Print' button is located at the bottom right of the page.

## STEP 6

Once the documents that you uploaded have been processed (i.e., you received the confirmatory email) you will go back to the NDI Notification Home Page and select “Retrieve Draft NDI” from the menu on the left hand side of the page (see **Figure 15** below). Type in your reference number supplied in the last page (**Figure 14**) and you will be taken to the preview page.


**Figure 15:**

The screenshot shows the 'New Dietary Ingredient (NDI) Notification' page with a left-hand navigation menu. The menu items are: 'NDI Home', 'Enter New Notification', 'Search Notification', 'Retrieve Draft NDIN' (highlighted in blue), 'Summary Reviewer Review', and 'Draft Letter'. The main content area is titled 'Retrieve Draft' and contains the text: 'Please enter the Draft ID to retrieve your saved NDI notification.' Below this text is a 'Draft ID' input field and a 'Retrieve Draft' button. The top of the page features the FDA NDI logo and the text '75 DAY PREMARKET NEW DIETARY INGREDIENT (NDI) NOTIFICATION'. The top right corner has links for 'FURLS HOME' and 'NDI HOME'.

## Preview Page

The NDIN review page is provided is shown in **Figure 16** below. You will still be able to edit your notification in future pages. To continue, click on the “Complete Draft” button in the lower right corner of the screen.

Figure 16:





75 DAY PREMARKET

NEW DIETARY INGREDIENT (NDI) NOTIFICATION

[FURLS HOME](#) | [NDI HOME](#)

New Dietary Ingredient (NDI) Notification

[NDI Home](#)
[Notification Review](#)

NDI Home

Enter New Notification

Search Notification

Retrieve Draft NDIN

Summary Reviewer Review

Draft Letter

### Notification Review

You have until **07/05/2015** to complete the draft notification. If you fail to submit the notification by **07/05/2015**, it will be removed.

### Section 1: Contact Information

Contacts List

Type	Name	Address
Submitter	ABCD	5100 Paint Branch Pkwy, College Park, MD 20740-3835 United States
Owner	ABCD	5100 Paint Branch Pkwy, College Park, MD 20740-3835 United States
Primary	John Doe	5100 Paint Branch Pkwy, College Park, MD 20740-3835 United States

Submitter

Type of Submitter

Manufacturer of NDI

Company Name (if applicable)

ABCD

Mailing Address Line 1

5100 Paint Branch Pkwy

Mailing Address Line 2

Country

United States

ZIP or Postal Code

20740-3835

City

College Park

State or Province

MD

Owner

Type of Submitter

Manufacturer of NDI

Company Name (if applicable)

ABCD

Mailing Address Line 1

5100 Paint Branch Pkwy

Mailing Address Line 2

Country

United States

ZIP or Postal Code

20740-3835

City

College Park

State or Province

MD

**Figure 16 Cont:**

Primary	
Type of Contact	Mailing Address
Submitter of the Notification	5100 Paint Branch Pkwy
First Name of Contact Person	Country
John	United States
Last Name of Contact Person	ZIP or Postal Code
Doe	20740-3835
Company Name	City
ABCD	College Park
Position	State or Province
	MD
Telephone Number	
001 402 2403652	
Fax Number	
Email Address	
john.doe@abcd.org	

## Section 2: General Administrative Information

1. Name of the New Dietary Ingredient
L. plantarum
2. Have you designated information in your notification that you view as a trade secret or as confidential commercial information?
No
3. Are you providing a redacted copy of some or all of the notification?
No
4. Are all citations to published information accompanied by reprints or full photostatic copies of the publications?
Yes
5. Are the notification and all publications submitted in English or accompanied by a complete and accurate English translation?
Yes

Figure 16 Cont:

Section 3: Description of NDI and Dietary Supplement Containing the NDI	
1. New Dietary Ingredient Type	
Dietary substance for use by man to supplement the diet by increasing the total dietary intake	
2. Name of the new dietary ingredient and related information	
Maximum level of new dietary ingredient in each serving of dietary supplement (include units)	
L. plantarum	
NDI Name	Latin Binomial Name (LBN)
L. plantarum	
	Author of LBN
Synonyms and Trade Name	
Plant Part and Strain	
3. Dietary supplement serving form	
Capsule	
4. Description of dietary supplement (Include the level of NDI and all other ingredients in one unit of the dietary supplement. If the notification concerns an NDI that is a combination of two or more other NDIs, you should provide the following information for each component NDI: Synonyms, Trade Name, Plant Part, Strain, Latin Binomial Name, Author of Latin Binomial Name, and NDI type. Where relevant, also include the following additional information: CAS registry number, Unusual form (e.g., malted barley or immature apples), Type of manufacture (e.g., greater than 99% purity, 50:1 dry leaf extract, or fermentation product)).	
1000 cfu	
5. Conditions of Use of the Dietary Supplement	
5a. Serving instructions (e.g., "take with food", "take before bed", "dissolve in a glass of water", etc).	
take with food	
5b. Dietary supplement serving size (weight or volumetric measure), serving frequency (# of servings/day, interval between servings), duration of use and maximum total daily intake level	
one capsule	
5c. Target populations / excluded populations / other restrictions	
adults	

**Figure 16 Cont:**

### Section 4: Safety Information Attachment

**Attachment**

Name of Attachment	Size (KB)	Date of Upload
NDIN help files.doc	1946.5	08/05/2015

### Section 5: Additional Attachments

**Attachment(s)**

Name of Attachment	Size (KB)	Date of Upload
step 1d.PNG	48.51	08/05/2015

[Back](#)[Complete Draft](#)[Discard Draft](#)[Print](#)

The following pages will repeat Steps 1-5 again and you will review the figures shown above. This will allow you to make any changes to your notification and click “Next” in the bottom right corner of the screen to continue through the submission process until you get to Step 6.

The NDIN review page is provided next (see Figure 17 below). Please review the information in your notification and correct any errors by clicking on the “edit” button at the top left side of each section.

Figure 17:

75 DAY PREMARKET

NEW DIETARY INGREDIENT (NDI) NOTIFICATION

[FURLS HOME](#) | [NDI HOME](#)

New Dietary Ingredient (NDI) Notification

[NDI Home](#) | [Retrieve Draft NDIN](#)

Step 1

Step 2

Step 3

Step 4

Step 5

Step 6

Step 7

Review the information for accuracy, edit if needed, and submit the notification.

NDI Home

Enter New Notification

Search Notification

Retrieve Draft NDIN

Summary Reviewer Review

Draft Letter

Section 1: Contact Information

Edit

Contacts List

Type	Name	Address
Submitter	ABCD	5100 Paint Branch Pkwy, College Park, MD 20740-3835 United States
Owner	ABCD	5100 Paint Branch Pkwy, College Park, MD 20740-3835 United States
Primary	John Doe	5100 Paint Branch Pkwy, College Park, MD 20740-3835 United States

Submitter

Owner

Type of Submitter

Manufacturer of NDI

Company Name (if applicable)

ABCD

Mailing Address Line 1

5100 Paint Branch Pkwy

Mailing Address Line 2

Country

United States

ZIP or Postal Code

20740-3835

City

College Park

State or Province

MD

Type of Submitter

Manufacturer of NDI

Company Name (if applicable)

ABCD

Mailing Address Line 1

5100 Paint Branch Pkwy

Mailing Address Line 2

Country

United States

ZIP or Postal Code

20740-3835

City

College Park

State or Province

MD

Primary

Type of Contact

Submitter of the Notification

First Name of Contact Person

John

Last Name of Contact Person

Doe

Company Name

ABCD

Position

Telephone Number

001 402 2403652

Fax Number

Email Address

john.doe@abcd.org

Mailing Address

5100 Paint Branch Pkwy

Country

United States

ZIP or Postal Code

20740-3835

City

College Park

State or Province

MD

Figure 17 Cont:

### Section 2: General Administrative Information Edit

- Name of the New Dietary Ingredient  
**L. plantarum**
- Have you designated information in your notification that you view as a trade secret or as confidential commercial information?  
**No**
- Are you providing a redacted copy of some or all of the notification?  
**No**
- Are all citations to published information accompanied by reprints or full photostatic copies of the publications?  
**Yes**
- Are the notification and all publications submitted in English or accompanied by a complete and accurate English translation?  
**Yes**

### Section 3: Description of NDI and Dietary Supplement Containing the NDI Edit

- New Dietary Ingredient Type  
**Dietary substance for use by man to supplement the diet by increasing the total dietary intake**
- Name of the new dietary ingredient and related information  
Maximum level of new dietary ingredient in each serving of dietary supplement (include units)  
**L. plantarum**  

NDI Name	Latin Binomial Name (LBN)
<b>L. plantarum</b>	Author of LBN
Synonyms and Trade Name	
Plant Part and Strain	
- Dietary supplement serving form  
**Capsule**
- Description of dietary supplement (Include the level of NDI and all other ingredients in one unit of the dietary supplement. If the notification concerns an NDI that is a combination of two or more other NDIs, you should provide the following information for each component NDI: Synonyms, Trade Name, Plant Part, Strain, Latin Binomial Name, Author of Latin Binomial Name, and NDI type. Where relevant, also include the following additional information: CAS registry number, Unusual form (e.g., malted barley or immature apples), Type of manufacture (e.g., greater than 99% purity, 50:1 dry leaf extract, or fermentation product)).  
**1000 cfu**
- Conditions of Use of the Dietary Supplement
  - Serving instructions (e.g., "take with food", "take before bed", "dissolve in a glass of water", etc).  
**take with food**
  - Dietary supplement serving size (weight or volumetric measure), serving frequency (# of servings/day, interval between servings), duration of use and maximum total daily intake level  
**one capsule**
  - Target populations / excluded populations / other restrictions  
**adults**

### Section 4: Safety Information Attachment Edit

Attachment

Name of Attachment	Size (KB)	Date of Upload
NDIN help files.doc	1940.5	05/05/2015



**Figure 17 Cont:**

**Section 5: Additional Attachments** [Edit](#)

**Attachment(s)**

Name of Attachment	Size (KB)	Date of Upload
step 1d.PNG	46.51	06/05/2015

[Print](#) [Save And Exit](#) [Next](#)

## STEP 7

### Section 6: Certification

All information must be completed for Section 6 (see **Figure 18** below) in order to submit your notification and receive a confirmation of receipt from FDA.

**Figure 18:**

**New Dietary Ingredient (NDI) Notification** [?](#) [Print](#)

[NDI Home](#) [Retrieve Draft NDIN](#)

[NDI Home](#)  
[Enter New Notification](#)  
[Search Notification](#)  
**[Retrieve Draft NDIN](#)**  
[Summary Reviewer Review](#)  
[Draft Letter](#)

[Step 1](#) [Step 2](#) [Step 3](#) [Step 4](#) [Step 5](#) [Step 6](#) [Step 7](#)

**Section 6: Certification**

By submitting this form to FDA, or by authorizing an individual to submit this form to FDA, the notification owner certifies that the information in the notification is true and accurate. Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

☐ I certify that the information in the notification is true and accurate and that I am authorized to submit the notification on behalf of the notification owner.

Name of Submitter

Title of Submitter

[Previous](#) [Save And Exit](#) [Submit](#)

After you submit the notification, you will be directed to a confirmation screen similar to **Figure 19** below.

**Figure 19:**

The screenshot shows the FDA 75 Day Premarket New Dietary Ingredient (NDI) Notification submission confirmation screen. The header is dark blue with the FDA NDI logo on the left, the text "75 DAY PREMARKET NEW DIETARY INGREDIENT (NDI) NOTIFICATION" in the center, and "FURLS HOME | NDI HOME" on the right. Below the header, the page title is "New Dietary Ingredient (NDI) Notification" with a red question mark icon and a printer icon to its right. A breadcrumb trail shows "NDI Home" and "Enter New Notification". On the left is a vertical menu with options: "NDI Home", "Enter New Notification", "Search Notification", "Retrieve Draft NDIN" (highlighted in blue), "Summary Reviewer Review", and "Draft Letter". The main content area is titled "Submission Confirmation" and contains a message: "Thank you for submitting your New Dietary Ingredient Notification. The NDI Number is 2015000171. You will receive an acknowledgement from the Center for Food Safety and Applied Nutrition when your submission has been processed." Below this, it says: "In order to receive notifications, please configure your email spam/junk to allow messages from NDITEAM@fda.hhs.gov." A blue "Print" button is located at the bottom right of the confirmation message box.

FDA NDI

**75 DAY PREMARKET**  
NEW DIETARY INGREDIENT (NDI) NOTIFICATION

FURLS HOME | NDI HOME

New Dietary Ingredient (NDI) Notification

NDI Home Enter New Notification

NDI Home

Enter New Notification

Search Notification

Retrieve Draft NDIN

Summary Reviewer Review

Draft Letter

**Submission Confirmation**

Thank you for submitting your New Dietary Ingredient Notification. The NDI Number is 2015000171. You will receive an acknowledgement from the Center for Food Safety and Applied Nutrition when your submission has been processed.

In order to receive notifications, please configure your email spam/junk to allow messages from NDITEAM@fda.hhs.gov.

Print